

Notice of Allowability

Application No.

10/527,481

Examiner

Hugh P. Young

Applicant(s)

DAVIS ET AL.

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Feb. 15, 2007.
2. ☒ The allowed claim(s) is/are 1.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

This is the second Office action on the merits of application No. 10,527,481. There is one claim pending, claims 2-11 having been cancelled by the Applicant. The Examiner's Amendment and comments below are directed towards Allowance of the claim.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Reid S. Willis of King of Prussia, PA, phone No. (610)-270-7481 on Thursday Feb. 15, 2007, and confirmed by a Facsimile of the amended claims sent to Examiner Young by Mr. Willis at 3:55 p.m. that same day.

The application has been amended as follows:

Amendment of the ABSTRACT:

The Examiner has amended the Abstract to be the following:

"A method is disclosed for the treatment of renal colic and associated pain, in humans or non-human mammals, comprising the administration of an effective, non-toxic and pharmaceutically acceptable amount of the vanilloid receptor antagonist *N*-(2-Bromophenyl)-*N'*-[((*R*)-1-(5-trifluoromethyl-2-pyridyl) pyrrolidin-3-yl] urea."

Amendment of the TITLE:

The Examiner has amended the Title of the Invention to be the following:

"Use of a ureidopyrrolidinyl vanilloid receptor antagonist for the treatment of renal colic pain."

Amendment of the CLAIMS:

Claim 1 has been amended to remove the final ")".

Claim 1 (Amended): A method for the treatment of renal colic and pain associated therewith, in human and non-human mammals, which method comprises the administration of an effective, non-toxic and pharmaceutically acceptable amount of N-(2-Bromophenyl)-N'-[(R)-1-(5-trifluoromethyl-2-pyridyl)pyrrolidin-3-yl]urea or a pharmaceutically acceptable salt thereof.

2. The following is an examiner's statement of reasons for allowance: the Applicant's claim is to a method of using a chemical compound for treatment of a particular medical condition, renal colic, and the pain associated with renal colic. The product used to practice the method of treatment claimed in the instant application is itself novel and free of the prior art; furthermore it is currently claimed as a product in a co-pending junior application by the Assignee, namely PCT/GB02/04206 (Formula I), published as WO 03/022809 A2 on 20 March 2003, as Example 1, page 33, line 1. In further review of the reasons for Allowance, the Examiner summarizes the status of earlier Rejections of the Claims as follows:

Rejections of claims 1, 2, 7, and 9 under **35 USC § 102(e)** made in the First Office Action on the Merits were addressed by Applicant by cancellation of claims 2, 7, 8, and 9 and the incorporation of the limitations of canceled claim 8 into the body of claim 1, thereby limiting the scope of claim 1 to the single chemical species named therein, thus removing claim 1 from the scope of the prior art cited by the Examiner.

Rejections of claims 1, 2, 7, 8 and 9 under **35 USC § 112**, first paragraph, made in the First Office Action on the Merits were addressed by Applicant by cancellation of claims 2, 7, 8, and 9 and the removal of the reference to prophylaxis or prevention of renal colic from claim 1, thereby limiting the scope of the remaining claim 1 to treatment of renal colic. Subsequent amendment by Applicant has removed references to non-elected diseases or disorders from claim 1.

Provisional rejection of claim 9 for nonstatutory obviousness-type double patenting over claims 1, 8, 9, 10, and 11 of copending application 10,540,100, made in the First Office Action on the Merits, was addressed by Applicant by cancellation of the instant claim 9. Simultaneous amendment by Applicant has, however, incorporated into claim 1 the limitation of the instant claim 8, namely the claim of the species of chemical compound that is used to practice the methods of

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treatment in the instant 10,527,481, thus rendering the amended instant claim 1 and claims 1, 8, 9, 10 and 11 of copending application 10,540,100 obvious over each other.

Because the provisional rejection for nonstatutory obviousness-type double patenting stated above is the only outstanding rejection, Examiner withdraws the rejection so that the instant (senior) application is Allowable. Applicant must be aware, however, that should the copending application 10,540,100 come to Allowance its claims, cited supra, would have to be amended, cancelled or a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) filed to overcome an actual or provisional rejection based on nonstatutory double patenting, provided there is still common ownership.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Nearest prior art of record

3. The Examiner has cited prior art in the first Office action pertaining to use of capsaicin, or vanilloid, receptor antagonists for the treatment of pain associated with the renal/urinary tract (Bakthavatchalam et al., WO/2002/008221), and chronic and acute pain, which are characteristic of kidney stone passage (renal colic) and hypersensitivity

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of the urinary bladder as well as inflammatory conditions of mucous membranes (Suh et al, WO/2002/016317). US Patents 3,424,760 and 3,424,761 teach the broad chemical group of 3-ureidopyrrolidines as having analgesic effects. Applicant's use of the instant *N*-(2-Bromophenyl)-*N'*-[*((R)*-1-(5-trifluoromethyl-2-pyridyl)pyrrolidin-3-yl)]urea is drawn to a novel composition which is disclosed and held by Applicant's assignee.

Conclusion

4. Claim 1 is allowed. All other claims (claims 2-11 as originally filed) are cancelled.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

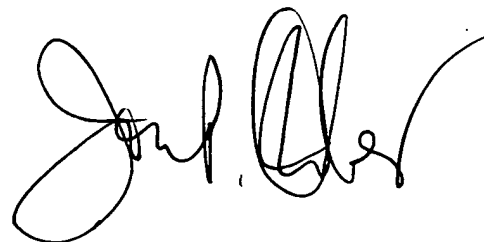
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Hugh Parker Young Ph.D.

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A handwritten signature in black ink, appearing to read 'Jon Weber', with a large, stylized initial 'J' and 'W'.

JON WEBER
SUPERVISORY PATENT EXAMINER